UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	MDL No. 2804
	)	Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:	)	Hon. Dan Aaron Polster
The Muscogee (Creek) Nation v. Purdue Pharma L.P., et al., Case No. 1:18-op-45459-DAP	)	

MEMORANDUM OF LAW IN SUPPORT OF GENERIC MANUFACTURERS' MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

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I. INTRODUCTION[1]

Plaintiff The Muscogee (Creek) Nation ("Plaintiff") seeks to recover a wide spectrum of public costs it allegedly incurred to address the opioid-abuse crisis from manufacturers of both generic and brand-name opioid medications approved by the federal Food and Drug Administration ("FDA") (collectively the "Manufacturers"). As explained in the Manufacturer Defendants' Joint Motion to Dismiss The Tribes' First Amended Complaints ("Joint MTD"), the claims against all Manufacturers are flawed as a matter of law. The Generic Manufacturers adopt and incorporate herein the arguments made in the Joint MTD. But the claims against the Generic Manufacturers are particularly flawed for additional threshold reasons. Generic drug companies are subject to different preemptive federal laws and regulations—and utilize a different business model—than their brand manufacturer counterparts. As a result, all claims against the Generic Manufacturers should be dismissed with prejudice under controlling Supreme Court and Sixth Circuit law.

First, Plaintiff does not and cannot plead any misconduct as to Generic Manufacturers. Plaintiff's First Amended Complaint ("FAC") primarily relies upon a false marketing theory, which requires Plaintiff to plead facts both to show that each Generic Manufacturer engaged in

[1] Pursuant to ¶ 2(g) in CMO 1 (ECF No. 232), KVK-Tech, Inc. ("KVK"), Amneal Pharmaceuticals, Inc. ("API"), Watson Laboratories, Inc. ("Watson"), Actavis Pharma, Inc. ("Actavis Pharma"), Actavis LLC ("Actavis"), Teva Pharmaceuticals, USA, Inc. ("Teva"), and Allergan Finance, LLC ("Allergan") (collectively the "Generic Manufacturers") raise certain key common issues that warrant dismissal of the claims against them, in addition to those arguments raised in the Joint MTD. Generic Manufacturers do not raise defendant-specific challenges and defenses, but expressly reserve their right to raise those at a later time consistent with CMO 1. (ECF No. 232, at ¶ 2(j).) That said, API is concurrently filing a Motion to Dismiss due to its unique improper party status, and although Plaintiff identifies Allergan as a Generic Marketing Manufacturer Defendant (FAC ¶157), Allergan is not actually responsible for marketing any generic opioid medicines. Nevertheless, Allergan joins this motion in light of Plaintiff's mistaken allegation, which must be taken as true. For purposes of this memorandum, emphasis in quotations is added, and internal citations, quotation marks, and alterations are omitted.

promotional activity and to provide the specific details of the supposed fraud. Yet, there are none. Plaintiff fails to identify a single interaction between any Generic Manufacturer and any prescriber in Oklahoma (or elsewhere); a single false or misleading statement made by any Generic Manufacturer; or a single opioid prescription that was somehow written because of a false or misleading statement made by any Generic Manufacturer.

The failure to plead these fundamental details is not surprising, given the well-recognized principle that Generic Manufacturers "compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York ex rel. Schneiderman v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. Dec. 11, 2014), *aff'd*, 787 F.3d 638 (2d Cir. 2015). Because Plaintiff fails to plead any of the fundamental details of any false marketing claim by any Generic Manufacturer, each of those claims should be dismissed.

Second, Plaintiff's state-law claims against the Generic Manufacturers for false marketing fail for the fundamental reason that they are preempted by federal law. The Federal Food Drug & Cosmetic Act ("FDCA") and its accompanying regulations prohibit a generic drug manufacturer from changing the design of a generic medicine, altering its FDA-approved labeling, or issuing additional warnings. Rather, the design and warnings of a generic drug must at all times be identical to those of its reference listed drug, typically a brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A). And that requirement extends to "[b]rochures, booklets, … price lists, catalogs" and "similar pieces of printed, audio, or visual matter descriptive of a drug . . . containing drug information supplied by the manufacturer." 21 C.F.R. § 202.1(*l*)(2). That "sameness" requirement was held to preempt state-law claims against generic drug manufacturers in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co.*,

v. Bartlett, 570 U.S. 472 (2013). Applying those decisions, the Sixth Circuit, as well as every other Circuit Court to address the issue, has held that state law claims requiring generic drug manufacturers to communicate information beyond the content of their labels are impliedly preempted because, in doing so, generic drug manufacturers would violate federal law. *See, e.g.*, *McDaniel v. Upshur-Smith Laboratories, Inc.*, 893 F.3d 941, 945-47 6th Cir. 2018); *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014); *Strayhorn v. Wyeth Pharma.*, 737 F.3d 378 (6th Cir. 2014).[2]

Here, the total lack of allegations that the Generic Manufacturers promoted generic medicines means Plaintiff's claims can be based only on the failure to disclose more than what is in the labels for those generic medicines. In particular, Plaintiff's claims are premised on a theory that the Generic Manufacturers did not sufficiently disclose the risks of opioids for chronic pain or take additional steps to correct unidentified statements made by other manufacturers about the use of opioids for chronic pain. (FAC ¶¶ 157-160.) Those claims all seek warnings and communications by the Generic Manufacturers beyond those in the labels of their generic medicines—actions that federal law expressly prohibits. Therefore, the claims are preempted.

Lastly, unable to plead false marketing claims against the Generic Manufacturers, Plaintiff resorts to conclusory allegations that the Generic Manufacturers did not report suspicious orders or prevent diversion. Those claims fail, too, for the reasons discussed in the Joint MTD (and in the *Summit County* motion to dismiss briefing), including that they are

[2] *See also Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2015); *Johnson v. Teva Pharm. USA*, 758 F.3d 605, 612 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014) (per curiam); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286 (10th Cir. 2013).

misguided attempts to enforce violations of federal law for which no private cause of action exists. Moreover, Plaintiff does not plead any facts demonstrating that any Generic Manufacturer failed to report a suspicious order, much less that any such order caused the Plaintiff any harm, particularly given the many intervening links in Plaintiff's highly-attenuated chain of causation, including the filling of such orders by pharmacies and the misuse of such prescriptions by Plaintiff's citizens.

In short, Plaintiff's claims against the Generic Manufacturers fail at the most basic level. Under controlling law, Plaintiff's claims should be dismissed with prejudice.[3]

II. BACKGROUND

Plaintiff alleges that KVK, API, Allergan, Teva, Actavis LLC, Actavis Pharma, and Watson Laboratories "are makers of generic prescription opioid products." (FAC ¶ 157.) Apart from background allegations (FAC ¶¶ 33-39, 41-42), however, the FAC contains ***no*** specific facts regarding any Generic Manufacturer. Instead, Plaintiff lumps the Generic Manufacturers with all other manufacturers under the label "Marketing Manufacturer Defendants" (FAC, ¶ 4), then contends that the Marketing Manufacturer Defendants engaged in a fraudulent marketing "campaign to misstate and conceal the risks of treating chronic pain with opioids." (*Id.*)

Yet, the manner in which generic drug companies operate is vastly different from the way brand-name drug companies market and promote their products. As multiple courts have recognized, generic drug manufacturers do not promote or advertise their generic medications to doctors or consumers; nor do they employ sales representatives to detail physicians about their generic pharmaceutical drugs. *See, e.g., Actavis, PLC*, 2014 WL 7015198 at *27; *Fulgenzi v.*

[3] Consistent with CMO 1, Generic Manufacturers have coordinated briefing and have "avoid[ed] duplicative briefing by incorporating similar arguments by reference." *Id.* at ¶2f.

PLIVA, Inc., 140 F. Supp. 3d 637, 650-651 (N.D. Ohio 2015) (summary judgment granted to generic drug manufacturer on all claims because evidence established prescribing doctor never saw labeling for generic product); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 111-112 (2008) (summary judgment granted to generic drug seller defendants based on undisputed facts that those defendants did not disseminate any information regarding their generic products to prescribing physician).

This business model is largely a result of drug substitution laws. A pharmacy's ultimate dispensing of a generic opioid medicine results from a doctor first choosing to write a prescription for his or her patient for a branded drug; the generic product is then substituted for the more expensive branded products by the pharmacist, provided the patient or the doctor permits that substitution. *See, e.g.*, Okla. Administrative Code §535:10-3-1.1(2) (requiring patient or doctor to give permission for pharmacist to substitute a generic). Currently, "all 50 states and the District of Columbia have drug substitution laws." *Actavis, PLC*, 787 F.3d at 644. As is the case for the Generic Manufacturers' generic opioid medications, there usually are multiple generic versions of a prescription medication, and a prescriber has no control over which generic manufacturer's product is substituted for the more expensive branded product. As a result, generic products are not marketed to prescribers and, in fact, marketing to prescribing doctors would be contrary to the generic business model, given that:

> Generics compete on price and avoid marketing to physicians because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete . . . In addition, because the generic [firm] promoting the product would have no way to ensure that its generic product, rather than an AB-rated generic made by one of its competitors, would be substituted for the brand by pharmacists, a substantial investment in marketing a generic product to physicians would not make sense as a practical matter.

See Actavis, PLC, 2014 WL 7015198, at *27.

Given this backdrop, Plaintiff's conclusory allegations of improper promotion by the Generic Manufacturers are implausible. Indeed, while claiming that all manufacturers made false misrepresentations about opioids to unidentified prescribers and consumers (FAC ¶¶ 104, 116, 120, 126), Plaintiff never identifies a single misrepresentation by any Generic Manufacturer. Instead, Plaintiff contends that the Generic Manufacturers—without differentiation—"failed to effectively and adequately communicate the warnings in the labels of their [opioid] products to physicians and patients." (FAC ¶ 157.) Plaintiff further contends that the Generic Manufacturers "owed a duty to effectively communicate clinically relevant information and warnings" regarding the "adverse health risks" of opioids and to "correct misstatements and misrepresentations made by name-brand opioid manufacturers . . . . " (FAC ¶¶ 157-158.) Based on those allegations, Plaintiff asserts false-marketing claims against all Generic Manufacturers for a violation of the Racketeer Influenced and Corrupt Organizations Act ("RICO") (Count I); violation of the Lanham Act (Count III); public nuisance (Count IV); negligence and negligence *per se* (Count V); unjust enrichment (Count VI); and civil conspiracy (Count X).

Plaintiff also asserts separate state-law claims against so-called "Diversion Defendants" (API and KVK-Tech), along with various distributors ("Distributor Defendants") and pharmacies ("Pharmacy Defendants"), based on an alleged failure to implement effective controls to prevent opioid diversion. (FAC ¶¶ 451-493.) Then, copying from pleadings in other lawsuits, Plaintiff alleges a RICO claim against all Generic Manufacturers based on that same diversion theory. (FAC ¶ 401.) Notably, Plaintiff does not identify a single suspicious order that any Generic Manufacturer failed to report—much less one that impacted Plaintiff in some way.

III. ARGUMENT

All of Plaintiff's claims fail for the reasons set forth in the Joint Motion. But as described below, Plaintiff's claims against the Generic Manufacturers should be dismissed for three additional and separate reasons: (1) ***no false marketing***—the FAC does not identify any alleged false marketing by the Generic Manufacturers, much less with the specificity required by Rule 9(b); (2) ***preemption***—the state law claims based upon false marketing are preempted by the FDCA as explained in controlling Supreme Court precedent; and (3) ***no failure to report/monitor***—Plaintiff fails to allege a single instance where any Generic Manufacturer failed to report or monitor a suspicious order, much less one connected to a prescription that caused some harm or expense to the Plaintiff.

A. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), Plaintiff must provide "more than labels and conclusions . . . . " *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Instead, the factual allegations must transcend the "speculative," "conceivable," and "possible," and must "state a claim to relief that is plausible on its face." *Id.* at 555–57, 566–67, 570. In making that determination, the Court must disregard "legal conclusions" and "conclusory statements," and must scrutinize the well-pleaded factual allegations to ensure that they are more than "'merely consistent with' a defendant's liability." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–79 (2009).

Moreover, because Plaintiff's claims rest on an alleged fraudulent campaign to market opioid medicines and a failure to report suspicious orders (FAC ¶¶ 4, 14, 326, 401), Plaintiff must satisfy Rule 9(b)'s particularity standard. *See Frank v. Dana*, 547 F.3d 564, 570 (6th Cir. 2008). To do so, Plaintiff must plead the "who, what, when, where, and how" of any alleged fraud, *Republic Bank & Tr. Co. v. Bear Stearns & Co.*, 683 F.3d 239, 256 (6th Cir. 2012),

including "the time, place, and content of the alleged misrepresentations," the "fraudulent scheme," "fraudulent intent," and "injury resulting from the fraud." *Sanderson v. HCA-The Healthcare Co.*, 447 F.3d 873, 877 (6th Cir. 2006).

B. Plaintiffs' Marketing Claims (Counts I, III, IV, V, VI, And X) Fail Because Plaintiff Does Not Allege Any False Marketing By The Generic Manufacturers, Much Less With The Specificity Required By Rule 9(b).

Plaintiff's claims are largely premised on allegedly fraudulent marketing activity. (FAC ¶¶ 358, 366-67 (Count I), 411-414 (Count III), 424 (Count IV), 436-438 (Count V), 450 (Count VI), 486 (Count X).) Yet, despite spanning 140 pages and 491 paragraphs, there are no facts in the FAC—let alone particularized facts—connecting the Generic Manufacturers to any purported false marketing. Indeed, Plaintiff does not allege a single fact against any Generic Manufacturer; not one single statement attributable to a Generic Manufacturer about one of its medicines. Nor is there an allegation of a single statement made by a Generic Manufacturer that reached an Oklahoma doctor, a tribal citizen who received an opioid prescription, or Plaintiff itself. Because of these core failures, the FAC certainly does not plead the requisite details of any fraudulent conduct, such as who made an allegedly false statement, when, to whom, and why it is purportedly false. Thus, all Plaintiff's false marketing claims fail as a matter of law. *See In re Darvocet*, 756 F.3d at 932 (affirming dismissal of false marketing claims against all "Generic Manufacturers" because plaintiffs failed to plead specific facts against each defendant to support legal theory); *see also City of Chi. v. Purdue Pharma L.P.*, No. 14-CV-4361, 2015 WL 2208423, at *4, *10 (N.D. Ill. May 8, 2015) (applying rule to dismiss similar claims against opioid manufacturers).

The only particularized allegations against the Generic Manufacturers consist of one statement concerning each Generic Manufacturer's alleged state of incorporation and principal

place of business in the "Background" section of the FAC, along with a conclusory claim that each Generic Manufacturer "manufactured and distributed substantial amounts of name brand prescription opioids and their generic equivalents . . . ." (FAC ¶¶ 33-37 (as to Actavis LLC, Actavis Pharma, Allergan, Watson, and Teva), ¶¶ 38-39, 41-42 (as to API and KVK).) Those allegations do not identify any alleged wrongdoing by any Generic Manufacturer or the specific details of any fraudulent conduct. Plaintiff does not even alert the Generic Manufacturers of the specific generic products as to which liability is sought to be imposed.

Plaintiff's allegations are devoid of the necessary details to state a claim plausible on its face. The reason is clear: Generic drug manufacturers do not promote or advertise their products to doctors or consumers, nor do they employ sales representatives to detail physicians about their generic pharmaceutical drugs. *See, e.g., Actavis, PLC*, 2014 WL 7015198, at *27; *see also Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637, 650-651 (N.D. Ohio 2015) (recognizing principle). As a result, there are no "facts" to plead. The Court need look no further than the "Factual Background" of the FAC, where Plaintiff only mentions two brand-name drug manufacturers (Endo and Purdue) by name. Although required to satisfy its pleading requirement, no particular allegations are made against any Generic Manufacturer. *See Iqbal*, 556 U.S. at 678 (requiring facts to show that each defendant "has acted unlawfully"); *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 505-06 (6th Cir. 2008) (dismissing claims for failure to satisfy Rule 9(b)).

With no allegations that the Generic Manufacturers promoted their generic medicines, Plaintiff cannot establish the most basic elements of its false marketing claims—misconduct, causation, or even a cognizable injury. Recognizing those deficiencies, Plaintiff turns to an omission theory—that the Generic Manufacturers did not communicate the warnings in their

labels to physicians and patients and did not "correct misstatements and misrepresentations made" by entirely distinct "name-brand opioid manufacturers." (FAC ¶¶ 157-58.) But, as described in Section III(B), federal law precludes the Generic Manufacturers from taking those actions.

Moreover, Plaintiff's non-disclosure theory defeats its own claims: It is a concession that the Generic Manufacturers' opioid labels adequately convey the risks associated with those medicines. Plaintiff never attacks the adequacy of the labels. (FAC ¶ 157.) Under Oklahoma law, a physician has a "duty to inform himself of the qualities and characteristics of those products which he administers or prescribes for use of his patients, and to exercise his judgment, based on his knowledge of the patient as well as the product." *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982). Those "qualities and characteristics" include the risks of abuse and addiction that are prominently disclosed in all FDA-approved labels for opioids;[4] and, under Oklahoma law, "if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise an informed judgment in the best interest of the patient." *Id.* at 25. Therefore, as a matter of well-settled Oklahoma law, Plaintiff cannot bring claims against the Generic Manufacturers for not providing additional information to physicians it never interacted with and who are obligated by law to know the adequately-disclosed risks in the labels of the medicines they prescribe. *Id.*

The same is true of Plaintiff's RICO claims. *See Ind./Ky./Ohio Reg'l Council of Carpenters Welfare Fund* v. *Cephalon, Inc.*, No. 13-7167, 2014 WL 2115498, at *6 (E.D. Pa. May 21, 2014) (dismissing RICO claims for fraudulent marketing because prescribers are

[4] *See* Branded Opioid Labels (ECF No. 499-5-13), attached as Exs. C-J to *Summit* MTD.

presumed to know a drug label's contents, which disclosed risks of opioids to "potential prescribing physicians"); *Travelers Indem. Co. v. Cephalon, Inc.*, 32 F. Supp. 3d 538, 553 (E.D. Pa. 2014), *aff'd*, 620 F. App'x 82 (3rd Cir. 2015) (dismissing fraud-based claims against opioid manufacturer for alleged false marketing because doctors are "sophisticated consumers who themselves have an affirmative duty to be familiar" with the labels of the medicines they prescribe).

Finally, trying to mask its inability to plead the fundamental and essential details against the Generic Manufacturers, Plaintiff lumps them together with five other, separate brand manufacturers under the name "Marketing Manufacturer Defendants," and then asserts hundreds of conclusory allegations about alleged improper marketing practices against that fictitious group, without distinction. (*See* FAC ¶¶ 4, 5, 40, 98-107, 109-10, 113, 116, 124-128, 130-132, 134-138, 143-144, 148-155, 157-161, 264, 268-273, 296-321, 328, 336, 353-374, 413, 415-16, 420-24, 427-31, 434-445, 447-450, 486, 488, 492.) Plaintiff also lumps certain Generic Manufacturers (KVK and API) with the Distributor and Pharmacy Defendants—entirely distinct entities and categories of Defendants—under the name "Diversion Defendants," and then asserts conclusory allegations against that mixed group without any differentiation. (FAC ¶¶ 14, 20, 98, 162-163, 165, 200, 335, 413, 415-416, 452-456, 459-462, 464, 466-478, 480-488.) That pleading tactic fails to state a claim as a matter of law because "[c]onclusory allegations of collective, unspecified, and undifferentiated wrongdoing is not sufficient: 'vaguely lump[ing] all defendants together without providing any factual allegations that specify separate acts' fails to satisfy the *Iqbal/Twombly* standard." *Kurek v. Ohio Dept. of Develop. Disabilities*, Case No. 3:16CV623, 2017 WL 1555930, at *6 (N.D. Ohio Jan 20, 2017).

Indeed, the Sixth Circuit repeatedly has rejected that very pleading strategy, dismissing

claims against generic drug manufacturers because the plaintiffs did not identify what specific manufacturers did what and provided "no factual basis" for their alleged claims and relied on "conclusory allegation[s]." *In re Darvocet,* 756 F.3d at 932; *see also Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (applying rule); *Windsor-Laurelwood Ctr. Behavioral Med. v. Waller Lansden Dortch & Davis*, Case No. 1:13-cv-00098, 2013 WL 12303992, at *5 (N.D. Ohio July 24, 2013) (same). This Court should do so the same.

C. Plaintiff's State-Law Marketing Claims (Counts IV, V, VI, And X) Against The Generic Manufacturers Are Preempted.

Plaintiff's state-law marketing claims against the Generic Manufacturers also should be dismissed because they are preempted by federal law. State-law claims that conflict with federal law are preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const., Art. VI, cl. 2; *Mensing*, 564 U.S. at 617 ("[w]here state and federal law 'directly conflict,' state law must give way") (citation omitted). There are two categories of federal preemption: express and implied. Implied preemption applies "where it is impossible for a private party to comply with both state and federal law . . . . " *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000) (citation omitted). It also applies whenever state law stands as "an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Yates v. Ortho-McNeil-Janssen Pharm., Inc.*, 808 F.3d 281, 294 (6th Cir. 2015)); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001).

Here, Plaintiff's state-law claims against the Generic Manufacturers are impliedly preempted. They are based on the Generic Manufacturers' product labels and alleged failure to provide additional warnings. (FAC ¶¶ 157-58, 160.) Those allegations are the only substantive allegations against the Generic Manufacturers throughout the FAC and are incorporated into each state-law claim. (FAC ¶¶ 419, 433, 446, 451.) Yet, federal law prohibits the Generic

Manufacturers from doing what Plaintiff contends they should have done under state law. Thus, the claims are preempted.[5]

1. Prescription Drugs Are Regulated Under The FDCA.

Prescription drugs are regulated under the FDCA, which is implemented and enforced by FDA. *See* 21 U.S.C. §§301 *et seq.*; *id.*, §§371, 393. A drug may not be marketed in interstate commerce unless an application has been approved by FDA. *See* 21 U.S.C. §355(a). Section 355(b) applies to new drugs and requires submission of a new drug application ("NDA"). In 1984, Congress amended the FDCA through the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly known as the "Hatch-Waxman Amendments"), which expands access to affordable generic drugs by reducing barriers to generic market entry. Pub. L. No. 98-417, 98 Stat. 1585 (1984); *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997).

2. The FDCA Prohibits The Generic Manufacturers From Providing Additional Or Different Warnings Beyond Their FDA-Approved Labels.

To achieve Hatch-Waxman's goal and facilitate entry of generic drugs into the marketplace, Congress drew sharp distinctions between the statutory and regulatory requirements for drugs approved under an NDA and generic drugs approved under an "abbreviated new drug application" ("ANDA").

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[5] The same analysis applies to Plaintiff's RICO Marketing Enterprise claim (Count I) against Generic Manufacturers. Although preemption involves "the question [of] whether state law is preempted by a federal statute," preemption principles are "instructive" in cases "concern[ing] the alleged preclusion of a cause of action under one federal statute" (here, RICO) "by the provisions of another federal statute" (here, the FDCA). *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). Generic Manufacturers cannot be penalized through a RICO claim for not doing what the FDCA prohibits.

Whereas previously both brand-name and generic drug manufacturers had to engage in "costly and lengthy clinical testing" to receive approval from FDA to market a medication, Hatch-Waxman allowed "manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Mensing*, 564 U.S. at 612. The trade-off for generic drugs receiving and maintaining FDA approval through that process, however, is that the FDCA requires all generic medications to be the same as their reference list drugs—typically a brand-name product—in every clinically significant way. *Id.* Generic medications therefore must have the same active ingredient(s) and therapeutic effect(s), the same route of administration, and—critically here—the same FDA-approved labeling as the brand-name medication. *See* 21 U.S.C. § 355(j)(2)(A).

Thus, the fundamental hallmark of Hatch-Waxman is "sameness": Generic drugs must hew to their reference list drug, and generic labeling—including its warnings and other safety-related information—must in all pertinent respects be "'the same as the labeling approved for the [brand-name] drug.'" *Mensing*, 564 U.S. at 612-13 (quoting 21 U.S.C. § 355(j)(2)(A)(v) and *citing id.* § 355(j)(4)(G) (alteration in original)). Indeed, under FDA's regulations, FDA may withdraw approval for a generic drug if "the labeling for the drug product that is the subject of the abbreviated new drug application is no longer consistent with that for the listed drug referred to in the abbreviated new drug application." 21 C.F.R. § 314.150(b)(10).

The "sameness" requirement goes further than just the physical label on the generic drug. The term "labeling" covers "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). In its regulations, FDA defines "labeling" to include "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters,

motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints" and "similar pieces of printed, audio, or visual matter descriptive of a drug . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer." 21 C.F.R. § 202.1(*l*)(2).

The "sameness" constraint on generic drug manufactures also applies post-approval**.** Although the FDCA does not expressly permit a manufacturer to change an approved drug's labeling without prior FDA approval,[6] brand manufacturers may, in certain circumstances, revise labeling before receiving FDA's approval to add or strengthen a "contraindication, warning, [or] precaution" through the changes-being-effected ("CBE") procedure. *Id.* § 314.70(c)(6). In contrast, generic manufacturers may not. They can use the CBE supplement only to change their labeling in narrowly circumscribed instances: "[T]o match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614. Outside those circumstances, "CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its brand-name counterpart's." *Id.* As such, "[f]ederal law . . . demand[s] that generic drug labels be the same at all times as the corresponding brand-name drug labels." *Id.* at 618.

In short, the well-established regulatory framework does not permit generic drug manufacturers to provide additional or different warnings for generic medicines beyond the confines of the FDA-approved label for their brand counterpart.

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[6] The FDCA prohibits introduction into interstate commerce of any drug not approved under §355. 21 U.S.C. §355(a). Any unapproved label change renders the drug a new, unapproved drug under the FDCA subject to the misbranding provisions. *See id.*

3. The Supreme Court Has Held That State-Law Claims Against The Generic Manufacturers Are Preempted.

Recognizing that a generic drug manufacturer cannot independently change its label under federal law to cure any alleged or perceived deficiencies in its warnings, the U.S. Supreme Court made clear that state-law claims that would require additional or different warnings or communications are preempted. In *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), the Supreme Court first held that state-law claims seeking to require generic drug manufacturers to change FDA-approved labeling are preempted because it is impossible for generic drug manufacturers to simultaneously comply with state-law requirements and the federal-law requirement of sameness. *Id.* at 618 ("Thus, it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same."). There, the plaintiffs alleged state-law failure-to-warn, fraud, and negligent misrepresentation claims against generic drug manufacturers of metoclopramide based on the manufacturers' alleged failure to provide adequate warning labels. *Id.* at 608–609. The Supreme Court recognized that the plaintiffs' claims would require the use of different labeling. *Id.* at 612. Federal law, however, did not allow them to make the change necessary to satisfy state law. As a result, the Supreme Court found the claims preempted. *Id.* at 618 ("***It was not lawful*** under federal law for the Manufacturers to do what state law required of them" because "state law imposed on the Manufacturers a duty to attach a safer label to their generic" drug, whereas federal law "demanded that generic drug labels be the same at all times as the corresponding brand-name drug labels.").

Notably, the *Mensing* Court expressly rejected the notion that manufacturers could

provide additional warnings through "Dear Doctor" letters to physicians,[7] holding that those letters are subject to the sameness requirement and cannot include updated or even additional warnings that stray from an approved label. *Id.* at 615. Doing so violates the sameness requirement because "if generic manufacturers, but not the brand-name manufacturers, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Id.* That ruling is based on a fundamental principle that federal law is supreme to any conflicting state law. *See* U.S. Const. art. VI, cl. 2. That *Mensing* is based on an outright conflict between the federal law governing generic drugs and state law is critical. It means that no state-law claims or alternative theories of liability based on product labeling for generic medicines, no matter how they are titled, survive preemption.

The Supreme Court reiterated its holding in *Mensing* two years later when it decided *Mutual Pharmaceutical Co., v. Bartlett*, 570 U.S. 472 (2013). In *Bartlett*, the Court reiterated that any state-law claim that brings into question the adequacy of, or otherwise affects a change in, a generic drug manufacturer's labeling is preempted. *Id.* at 486-487, 490. The plaintiff in *Bartlett* asserted a design defect claim under New Hampshire state law against a generic drug manufacturer based on severe side effects the plaintiff experienced after taking the generic form of a drug. *Id.* at 478. After first holding that design defect claims involving pharmaceutical products are preempted because manufacturers cannot change the chemical composition of a drug, the Supreme Court ruled that the only way to satisfy the state-law duty would be to change the product's labeling. The Supreme Court held that the plaintiff's claim was preempted

[7] "Dear Doctor" letters are communications used by manufacturers to notify health care providers about new or updated warnings regarding a drug. *See* 21 C.F.R. § 200.5 ("Manufacturers and distributors of drugs and the Food and Drug Administration occasionally are required to mail important information about drugs to physicians and others responsible for patient care.").

because, as in *Mensing*, the generic drug manufacturer could not make that labeling change under federal law. *Id.* at 482, 490 (recognizing design defect claims only could "be satisfied either by changing a drug's design or by changing its labeling" and holding claim preempted because federal laws prohibit manufacturers from unilaterally altering drug composition or labeling).

Mensing and *Bartlett* apply to more than just causes of action premised on design defect or inadequate warnings—they reach all causes of action against generic drug manufacturers premised on a state-law duty that involves labeling. Applying *Mensing* and *Bartlett*, the Sixth Circuit and district courts in the circuits repeatedly have held that state-law claims under a wide variety of theories against generic drug manufacturers are preempted, including claims for failure to warn, false marketing, failure to communicate, failure to confirm, and statutory negligence. *See, e.g.*, *McDaniel v. Upsher-Smith Pharmaceuticals, Inc.*, 229 F. Supp. 3d 707, 711 (W.D. Tenn. 2017) (failure to warn claims based upon alleged failure to provide Medication Guide preempted); *In re Darvocet*, 756 F.3d at 930-936 (failure to warn, breach of warranty, fraud, misrepresentation, consumer protection, and negligence claims based upon a broad range of labeling-related challenges preempted); *Strayhorn*, 737 F.3d at 390-397 (6th Cir. 2013) (civil conspiracy, failure to conform, and failure to warn claims based, in part, upon failure to provide additional information preempted); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 423 (6th Cir. 2011) (state law failure to warn claims preempted based on allegedly inadequate information on product labels).

Given the broad scope of *Mensing* preemption, the Sixth Circuit recognizes that "claims [that] boil down to an alleged duty to provide additional information" for generic medicines—apart from what is in the label of those medicines—are "essentially failure-to-warn claims that

are preempted under *Mensing*." *Strayhorn*, 737 F.3d at 397. Those controlling principles apply to and bar Plaintiff's state-law marketing claims against the Generic Manufacturers.

4. Plaintiff's State-Law Marketing Claims Against The Generic Manufacturers Are Incompatible With Federal Law And Are Preempted.

Plaintiff purports to bring state-law negligence, unjust enrichment, and civil conspiracy claims against the Generic Manufacturers based on alleged false marketing. (FAC ¶¶ 419-50, 485-88.) As discussed, however, Plaintiff does not allege a single false or misleading statement by any Generic Manufacturer. Instead, Plaintiff alleges that the Generic Manufacturers failed to warn about the risks of opioids to doctors and patients, including by failing to communicate "clinically relevant information and warnings" and to "correct [unidentified] misstatements and misrepresentations made by name-brand opioid manufacturers." (FAC ¶¶ 157-58, 160.) Those failure-to-warn allegations are incorporated into each state-law claim against the Generic Manufacturers. (FAC ¶¶ 419, 433, 446, 451.)

Those claims fall precisely within the category of state-law claims that are preempted under *Mensing* and *Bartlett* because the Generic Manufacturers may not provide ***additional*** information regarding their generic medicines, apart from what is in the product label. *See Strayhorn*, 737 F.3d at 396-97. Yet, Plaintiff contends that the Generic Manufacturers should have provided information ***beyond*** the labels of their medicines to warn physicians and patients about the risks of opioids for long-term chronic plain. Plaintiff's legal theories would require the Generic Manufacturers to provide different safety warnings regarding the risks posed by unidentified opioid medications in order to avoid liability—an impossible request in light of the federal "sameness" requirements. *See, e.g.*, *In re Darvocet*, 756 F.3d at 935-36 (rejecting fraud, misrepresentation, and consumer protection claims against generic manufacturer as preempted

because the claims "all challenge label content" and "Plaintiffs do not identify any representations made [by generic manufacturers] other than those contained in the FDA-approved labeling").

Plaintiff tries to avoid preemption by alleging that the Generic Manufacturers could have provided additional communications to physicians that "did not require language different from the approved FDA label." (FAC ¶ 158 (alleging Generic Manufacturers failed to send "doctors and healthcare providers letters . . . which highlighted and explained the products' warnings, labeling, and other information.").) The Supreme Court, the Sixth Circuit, and other courts disagree. Numerous decisions, starting with *Mensing*, make clear that such failure-to-communicate claims—which, here, purportedly would include the unidentified "clinically relevant data or information" about the risks of generic medicines that the Plaintiff accuses the Generic Manufacturers of not providing (FAC ¶ 160))—are preempted. *Mensing*, 564 U.S. at 516; *In re Darvocet*, 756 F.3d at 932; *Morris v. PLIVA*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino v. Wyeth*, LLC, 719 F.3d 1245, 1249 (11th Cir. 2013); *see also Fulgenzi*, 140 F. Supp. 3d at 652-653 (holding state law claims against generic manufacturers for failure to unilaterally communicate updated label change to physicians were preempted and foreclosed by *Mensing* because "the generic manufacturers were not free to pursue other forms of communication to disseminate this information.").

In *Darvocet*, for instance, the Sixth Circuit addressed claims that generic drug manufacturers did not send "Dear Doctor" Letters to healthcare professionals regarding propoxyphene's risks. 756 F.3d at 932. The Sixth Circuit rejected the claim, making clear that requiring generic drug manufacturers to provide any additional information about the risks of the medicines—apart from what any brand manufacturers sent—would "violate the duty of

sameness." *Id.* at 933. The Sixth Circuit, agreeing with the Eleventh Circuit and Fifth Circuit, emphasized that:

> Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, ***not whether the proposed warning to be disseminated contains substantially similar information as the label***. Because no brand-name manufacturer sent a warning . . . the generic manufacturers were not at liberty to do so.

Id. The same is true here. The Generic Manufacturers could not have unilaterally sent any additional communications or warnings regarding its generic opioids because they were prohibited under federal law from doing so. *See also Guarino*, 719 F.3d at 1249 (applying rule to affirm dismissal of similar claims).

Nor can Plaintiff escape preemption by alleging in conclusory fashion that the "tort claims rest on traditional state principles that parallel federal safety requirements but do not exist solely by virtue of the FDA laws and regulations." (FAC ¶ 159.) *Mensing* precludes that argument. Like Plaintiff here, the *Mensing* plaintiffs asserted that federal law did not preempt their state-law claims because "Defendants were prohibited by federal law, as by state law, from selling their products with inadequate warnings." (Brief of Respondents, *Mensing*, 2011 WL 686400, at *29 (citing 21 U.S.C. § 352(f)(2); 21 U.S.C. § 331; 21 C.F.R. § 201.57).) Notwithstanding the repeated invocation of the parallel claims theory, the *Mensing* Court rejected the plaintiffs' claims against the generic manufacturer as preempted, thereby making clear that this argument does not constitute an exception to well-settled implied preemption principles. *Mensing*, 564 U.S. at 617-18. The Sixth Circuit has consistently applied *Mensing* to find preempted the types of claims at issue here. *Strayhorn*, 737 F.3d at 396-97. This Court should do the same.

Put simply, all Plaintiff's state-law false marketing claims against the Generic Manufacturers are at bottom allegations regarding the Generic Manufacturers' failure to warn about the risks of long-term opioid use, notwithstanding that such risks are clearly disclosed in the labels for the generic medicines at issue. Those claims "therefore cannot escape *Mensing's* grasp." *Guarino*, 719 F.3d at 1249.

D. Plaintiff's Claims (Counts II, VII, VIII, And IX) Based Upon Its Failure To Prevent Diversion Theory Fail, Too.

Plaintiff also asserts RICO claims against all Manufacturers, and certain state law claims against API and KVK, based upon a theory that they failed to monitor, report, and halt suspicious orders of opioid medications in violation of federal and state reporting laws. (FAC ¶¶ 401-02, 405, 452, 459, 467-68, 475, 480.) Those claims rest on the same flawed allegations asserted in *Summit County*, and, therefore, they fail as a matter of law for the reasons expressed in the Joint Motion and the motion to dismiss briefing in *Summit County*:

- ***No RICO "Supply Chain" Claim* (Count II).** Plaintiff has not pled any RICO predicate act to support its failure-to-prevent-diversion theory, a RICO "Supply Chain Enterprise," actual or proximate causation, or a cognizable RICO injury. Joint MTD Part I, II.C, V.A.2; *Summit* Manufacturer Joint Motion To Dismiss ("*Summit* MTD"), ECF No. 499-1, at 28-34.

- ***No Private Cause Of Action* (Counts II and VII-IX)**. Plaintiff's claims are based upon the alleged failure to monitor, report, and halt suspicious orders in violation of the Controlled Substances Act ("CSA") and Oklahoma Uniform Controlled Substances Act ("OCSA") (FAC ¶¶ 162-169, 178-185), which are incorporated into each count. (*Id.* ¶¶ 380, 451, 465, 479). But there is no private cause of action to enforce the CSA, OCSA, or any implementing regulations, and Plaintiff cannot use either RICO or common law theories to circumvent that legislative intent. Joint MTD Part II.A.F; *Summit* MTD, at 27-28, 47-48; *Summit* Distributor Joint Motion To Dismiss, ECF No. 41-1, at 36-38.[8]

[8] The Sixth Circuit has held that permitting a plaintiff to enforce statutory or regulatory duties through common law negligence (and other common law claims) is improper because it "would, in effect, be permitting a private cause of action under" a statute or regulation that does not allow for one. *Myers v. United States*, 17 F.3d 890, 901 (6th Cir. 1994); *see also McKesson Corp. v. Hembree*, No. 17-CV-323, 2018 WL 340042, at *5 (N.D. Okla. Jan. 9, 2018) ("[C]ourts have

- ***Preemption* (Counts VII-IX)**. Plaintiff's state-law claims are no more than fraud-on-the-DEA claims, based upon the alleged failure to report diversion. Because those claims conflict with the exclusive enforcement authority of the federal government (*i.e.*, DEA), they are impliedly preempted under the controlling logic of *Buckman* and Sixth Circuit law. *See Buckman Co.*, 531 U.S. at 348-50; *In re Darvocet*, 756 F.3d at 936; *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 423 (6th Cir. 2005); Joint MTD Part IV; *Summit* MTD, at 36-38.

- ***Failure To Plead Core Elements* (Counts VII-IX)**. Plaintiff has not pleaded any of the key elements of its state-law claims based upon this theory, including any misconduct, causation, or a cognizable injury. Joint MTD Part I-IV; *Summit* MTD, at 40-53.

For each reason, the claims fail against all Manufacturers. But, as with Plaintiff's false marketing claims, the claims are particularly flawed as to the Generic Manufacturers for yet another reason: In the sections pertaining to Plaintiff's diversion theory (FAC ¶¶ 162-294), there is not a single factual allegation pleaded against any Generic Manufacturer. As such, the FAC fails to identify a single suspicious order that any Generic Manufacturer failed to report; a single misleading statement or omission by any Generic Manufacturer regarding any federal or state diversion monitoring obligation (much less when they were made and to whom); or how any alleged failure to report by any Generic Manufacturer caused some harm to any citizen of Plaintiff, as opposed to the actions of the many other independent actors that break the causal chain. Indeed, it is clear from the FAC that the claims are directed to the Pharmacy and Distributor Defendants—not any manufacturer of generic medicines. (FAC ¶¶ 200-262.) For that reason alone, the failure to prevent diversion claims should be dismissed.

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rejected private attempts to enforce the CSA through other vehicles."). The same general principle applies under Oklahoma law. *Public Service Co. of Oklahoma v. A Plus, Inc.*, No. CIV–10–651–D, 2011 WL 3329181, at *8 (W.D. Okla. Aug. 2, 2011) (applying principle to dismiss state law claims); *Paulson v. Sternlof*, 15 P.3d 981, 984 (Okla. Civ. App. 2000) (same).

IV. CONCLUSION

For all the reasons articulated herein, in the corresponding Joint Motion to Dismiss, and the incorporated portions of the *Summit County* motion to dismiss briefs, all claims against the Generic manufacturers should be dismissed with prejudice.

Dated: August 31, 2018

Respectfully submitted,

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LOCAL RULE 7.1(F) CERTIFICATION

I certify that this case has been assigned to the "litigation track" pursuant to CMO One and that this Memorandum adheres to the page limitations set forth in CMO One § 6(f), CMO Four at 2-3, L.R. 7.1(f), and the Court's July 26, 2018 Order (Dkt. 791).

Dated: August 31, 2018

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CERTIFICATE OF SERVICE

I hereby certify that on August 31, 2018, a copy of the foregoing **Memorandum Of Law Support Of Generic Manufacturers' Motion to Dismiss Plaintiff's First Amended Complaint** was filed electronically in MDL Master Docket No. 17-md-2804 and in No. 1:18-op-45459-DAP. Notice of this filing was sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

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